

**REMARKS**

Applicants have cancelled claims 2, 5 and 14 without prejudice expressly reserving the right to pursue the subject matter of the cancelled claims in one or more subsequently filed applications.

Applicants have amended claims 1, 4 and 13 to recite that the essential amino acid is selected from the group consisting leucine, isoleucine, valine and mixtures thereof. Support for this amendment is found e.g. in claims 2, 5 and 14 and page 4, lines 5-10.

Applicants have also amended claims 1, 4 and 13 to recite that the amino acids are administered in an amount sufficient to suppress prion protein proliferation. Support for this amendment is found e.g. on page 6, lines 22 to -23, which states, "...can be any amount sufficient to suppress proliferation of abnormal prion protein."

Claims 1-9 and 13-19 stand rejected under 35 U.S.C. § 103(a) for purportedly being obvious over Richardson (WO 96/21437) in view of Gordon (WO 00/64420). Applicants disagree and in view of the amendments to the claims and the following remarks request that the Examiner reconsider and withdraw the rejection.

Applicants' claims relate to a method for suppressing proliferation of abnormal prion proteins in a subject by administering essential amino acid having a branched side chain. The present claims recite that the amount of the

essential amino acids must be sufficient to suppress proliferation of the prion proteins and that the essential amino acid is selected from the group consisting of isoleucine, leucine, valine and mixtures thereof.

Richardson teaches treating subjects with TD symptoms with leucine, isoleucine and valine with phenylalanine and tyrosine (see e.g., claim 1), and while Richardson may disclose that branch chain amino acids or aromatic amino acids may be used to alleviate abnormal movement disorders seen as a symptom of a primary neurological disorder or disease, Richardson fails to teach that (i) such branch chain amino acids would suppress prion proliferation, (ii) that the amounts sufficient to alleviate abnormal movements would suppress prion protein proliferation and (iii) fails to teach or suggest the administration of a particular branch chain amino acid, i.e., leucine, isoleucine and or valine, or mixtures thereof, with or without phenylalanine or tyrosine would suppress prion proliferation.

Moreover, Richardson et al. merely recites Creutzfeld Jakob disease (CJD) in a laundry list of diseases but only assays the effect of any essential amino acids on abnormal movement disorders that arise secondary to treatment with neuroleptics. Richardson does not assay the effect of any essential amino acid on any disease such as CJD and acknowledges the “complexities of treatment in this field...” page 42, line 25. Thus one of skill in the art could not reasonably predict from Richardson’s disclosure that administering the particular branch chain amino acids, i.e., leucine, isoleucine and valine, in an amount sufficient to

alleviate abnormal movement would have any effect on CJD. Nor would one of skill in the art reasonably predict that the particular amino acids would suppress prion proliferation.

In In Re Kubin (Fed Cir 2009), the court outlined two classes of situations where “obvious to try” is erroneously equated with obviousness under § 103. In the first class of cases:

what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. ... In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.

This class of impermissible hindsight is applicable to Applicants’ claimed invention. At the time of this invention, prion diseases such as scrapie, BSE and GSS were long known and studied, but no effective treatment to suppress the proliferation of prion proteins had been reported. Thus the prior art as a whole and Richardson in particular at the time of this invention gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. Therefore the prior art does not render the invention as claimed obvious.

The court In Re Kubin (Fed Cir 2009) also outlined a second class of situations where “obvious to try” is erroneously equated with obviousness under §103;

The second class of O'Farrell's impermissible "obvious to try" situations occurs where what was "obvious to try" was to explore . . . or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. 853 F.2d at 903.

Cited in In re Kubin (Fed Cir 2009)

This second class of impermissible hindsight reconstruction is also applicable here. Richardson at best only provides a general approach that may have seemed a promising field of experimentation in the treatment of abnormal movement disorders that were secondary to treatment with neuroleptics, but does not provide any insight into a method for the suppression of prion proliferation. Thus Richardson fails to render the invention as claimed obvious: And Gordon does not compensate for Richardson's deficiencies.

Gordon et al. discloses that CJD is characterized by the appearance and accumulation of prion protein but like Richardson et al. does not teach or suggest that administering essential amino acids selected from the group consisting of leucine, isoleucine or valine in any amount would have any effect on suppressing prion proliferation. In fact, Gordon teaches the administration of their particular inventive compounds, and not leucine, isoleucine or valine, for the treatment of amyloidosis (see e.g., page 2, line 16 to page 17, line 16) Therefore the combination of Richardson and Gordon fail to suggest suppression prion proliferation by administering an essential amino acids leucine, isoleucine or valine or mixtures thereof in an amount of that is sufficient to suppress prion

protein proliferation, and as such fails to render the invention as claimed obvious.

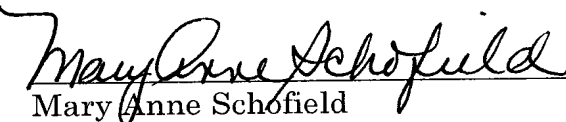
In view of the foregoing amendments and remarks, Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a) over the combination of Richardson and Gordon.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket # 101551.55779US).

Respectfully submitted,

August 17, 2009

  
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